

## REMARKS/ARGUMENTS

### I. Rejection under 35 U.S.C. §103(a):

The Examiner has rejected claims 1-42 as being unpatentable under 35 U.S.C. §103(a) over U.S. Pat. No. 6,102,957 to Noble, et al. (hereinafter “Noble”). Claims 1, 10 and 21 are independent. For the following reasons, the Applicants respectfully traverse this rejection.

Claim 1 is directed to a prosthetic femoral implant comprising a stem, a neck portion, and a femoral head. Claim 1 further specifies certain dimensional characteristics of a transverse cross-section of the neck portion. Potential benefits of a preferred embodiment of the claimed invention are set out, among other places, in paragraph 11 of the application as filed. There, Applicants explained that the novel neck portion “is designed to provide an improved balance between the range of motion of the joint during common activities and the resistance of the device to mechanical failure through its neck portion.”

Applicants’ respectfully submit that the Examiner’s rejection of claim 1 as obvious in view of Noble is based upon an incorrect reading of the Noble reference and a misunderstanding of the Applicants’ claims. Noble teaches preferred configurations of the intramedullary section of a femoral stem implant – the section of the hip implant that is embedded in the femoral intramedullary canal. Noble, however, is silent regarding cross-sectional designs of the neck portion of the implant.

As understood in the art, and explained by Noble, a femoral stem consists of two distinct sections, namely an intramedullary section and an extramedullary section. The intramedullary section is contained within the shaft of the femur and is configured to provide fixation of the prosthesis with respect to the bone through contact with the bony walls of the intramedullary canal. The extramedullary section protrudes beyond the cut surface of the proximal femur, and includes, among other things, the neck. Notably, the neck comes into contact with the acetabular prosthesis at the extremes of joint motion, and thus provides a limitation on the usable range of motion of the artificial joint. The neck must therefore be designed to balance the desire to increase range of motion with the strength constraints required to prevent failure of the prosthesis. In contrast, the intramedullary section of the hip implant, which is the focus of the Noble reference, is *embedded* within the femur and at a location removed from the joint. Increasing range of motion is not a relevant concern in designing this section.

The Examiner specifically cites column 5, line 54 of Noble in rejecting the Applicant’s claims. (Examiner’s Action, page 2). This particular section in the Noble reference, however, actually describes

a model (10<sup>1</sup>) of the internal surface of the femur, as further illustrated in Figs 2 and 2A of Noble. The model (10<sup>1</sup>) (as well as the stem (10)), referenced in Noble (i.e. shown in Fig. 2) does not have a neck, so it is impossible to deduce anything relating to a neck from this particular referenced section in Noble. This stem model illustrated in Noble is utilized to generate the shape of the intramedullary section of a femoral prosthesis through the removal of all material above the sloped line (21b) (see Col. 5, line 57). Accordingly, none of the material along the medial aspect of the model would in fact remain to be incorporated into the neck segment of the prosthesis derived from this model. This is further reiterated by the following statement in Noble (Col. 5, line 58): “The prosthetic neck is then added to the sloped surface.” It is also important to recognize that all of the cross--sections (e.g. A-A, B-B, etc.) illustrated in Noble have been taken perpendicular to the longitudinal axis of the body (i.e. perpendicular to the axis Z), and not perpendicular to any neck axis, including axis F, illustrated in Fig 1. Only the perspective views of the Noble stem given any suggestion as to what the cross-sectional shape of the neck portion of the hip stem is, that shape being “circular,” as best illustrated in Fig. 1A. Such a circular configuration is entirely consistent with much of the prior art, and significantly different from the Applicants’ claimed implant with respect to the cross-sectional configuration of the neck portion.

For at least the foregoing reasons, the Noble reference does not teach or suggest the limitations in claim 1 regarding the transverse cross of the neck portion of the femoral implant. Therefore, the rejection of claim 1 as obvious in view of Noble is improper.

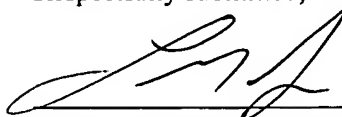
Like claim 1, independent claims 10 and 21 are directed to femoral implants comprising a stem, a neck portion, and femoral head. Also like claim 1, claims 10 and 21 further specify parameters of a transverse cross-section of the neck portion. Thus, for at least the reasons described above with respect to claim 1, Applicants respectfully submit that the rejections of claims 10 and 21 in view of Noble are improper.

Finally, dependent claims 2-9, 11-20, and 22-42 were also rejected. Because the independent claims from which they depend should be allowable as described above, all of these dependent claims should be allowable, as well.

II. Conclusion:

In view of the foregoing remarks, it is respectfully submitted that claims 1-42 are not rendered obvious by the cited art, and thus are in proper condition for allowance. Withdrawal of the Examiner's rejection is respectfully requested.

Respectfully submitted,



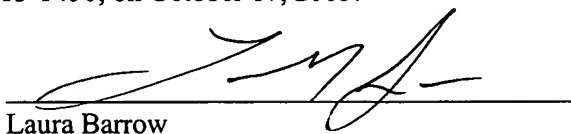
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CERTIFICATE UNDER 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on October 17, 2005.

  
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